

MAY 2 5 2000

Dr. Albert Zickmann

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510(K) Summary

K000633

General Information

Classification Name:	Endosseous Implant for Bone Filling and/or Augmentation
Common Name:	Bio-active Glass Synthetic Bone Graft Particulate
Trade Name:	Synthetic Glass Bone Graft Material
Submitter's Name:	Dr. Albert Zickmann
Address:	5455 N Sheridan Road, #3608 Chicago, IL 60640
Telephone:	(773) 769 2622
Fax:	(773) 878 8884
Contact:	Dr. Albert Zickmann
Date of Summary:	February 2000

Device Description

Synthetic Glass Bone Graft Material is a synthetic osteoconductive particulate bone/void filler that is intended for oral/maxillo-facial and dental intraosseous defects use. The material is composed of Bio-active Glass (SiO_2 , CaO , P_2O_5 and Na_2O) with the particle size range of 90-710 micrometers.

Predicate Devices

Synthetic Glass Bone Graft Material has been shown to be substantially equivalent to BioGran™ (K952922) and PerioGlas® (K992416 and K930115) as a bone graft material for reconstruction and augmentation of the alveolar ridge. Any minor differences which might exist between Synthetic Glass Bone Graft Material and its predicate devices do not raise new questions of safety or Effectiveness.

Intended Use

Synthetic Glass Bone Graft Material is intended to fill and/or augment dental intraosseous and oral/maxillofacial defects including:

- Periodontal defects
- Sinus lifts
- Ridge augmentation
- Cranio-facial augmentation
- Extraction sites
- Traumatic defects of the alveolar ridge excluding maxillary and mandibular fractures
- Defects of endodontic origin
- Cystic defects



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 25 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Albert Zickmann
C/O Ms. Rita Giebel
Holland & Associates
3722 Avenue Sausalito
Irvine, California 92606

Re: K000633
Synthetic Glass Bone Graft Material
Regulatory Class: Unclassified
Product Code: LYC
Dated: February 23, 2000
Received: February 25, 2000

Dear Ms. Giebel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

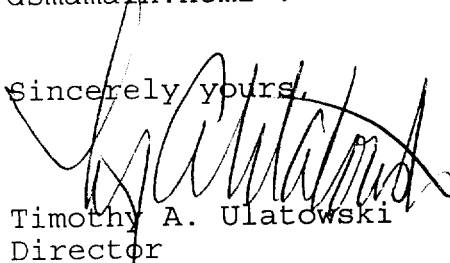
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4692. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Dr. Albert Zickmann

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Indications for Use Statement

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510(k) Number (if known): K000633

Device Name: Synthetic Glass Bone Graft Material

Indications for Use:

The intended use for Synthetic Glass Bone Graft Material is to provide a synthetic bone Graft material for oral/maxillofacial and dental intrasosseous defect use. Typical uses include:

- Ridge augmentation
- Sinus lifts
- Filling of Cystic defects
- Filling of Extraction sites
- Cranio-facial augmentation
- Repair of Traumatic defects of the alveolar ridge excluding maxillary and mandibular fractures
- Filling of Lesions of Periodontal Origin
- Filling of Defects of Endodontic Origin

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K 000633

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The Counter Use
(Optional Format 1-2-96)